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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,644	03/27/2002	David M. Hodgson	PT-1086 USN	3201

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Applicati n N .

10/089,644

Applicant(s)

HODGSON ET AL.

Examiner

David J Steadman

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-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . 6) ☐ Other: ____.

DETAILED ACTION

Status of the Application

- [1] Claims 1-19 are pending in the application.
- [2] The specification is objected to as a hole is punched through the text of claim 7. It is suggested that applicant submit a replacement page 93 of the application.
- [3] It is noted that claims 7-8 are dependent upon claim 5. However, there is no recitation of the term "probe" in claim 5 and it appears that claims 7-8 should depend from claim 6 instead. In the interest of advancing prosecution, claims 7-8 have been restricted as though they depend from claim 6.
- [4] It is noted that the title of the application as stated on the Transmittal Letter filed March 27, 2002, is "Secretory Molecules", while the corresponding specification indicates that the title is "Molecules for Disease Detection and Treatment". In order to clarify the record, the examiner requests that applicants clarify this discrepancy in the application.

Lack of Unity

- [5] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Groups I-XXV, claims 1-5, 9-10, and 16, drawn to the special technical feature of an isolated polynucleotide, a composition thereof, a cell, the first claimed method of use, i.e., a method for detecting a target polynucleotide, and a microarray. Group I recites

SEQ ID NO:1, Group II recites SEQ ID NO:2, Group III recites SEQ ID NO:3,... ..and Group XXV recites SEQ ID NO:25.

Groups XXVI-L, claim 11, drawn to the special technical feature of a transgenic organism. Group XXVI recites SEQ ID NO:1, Group XXVII recites SEQ ID NO:2, Group XXVIII recites SEQ ID NO:3,... ..and Group L recites SEQ ID NO:25.

Groups LI-LXXV, claims 12-13 and 15, drawn to the special technical feature of a purified polypeptide, a method for making a polypeptide, and the first claimed method of use, i.e., a method for identifying a test compound. Group LI recites a polypeptide encoded by SEQ ID NO:1, Group LII recites a polypeptide encoded by SEQ ID NO:2, Group LIII recites a polypeptide encoded by SEQ ID NO:3,... ..and Group LXXV recites a polypeptide encoded by SEQ ID NO:25.

Groups LXXVI-C, claim 14, drawn to the special technical feature of an isolated antibody. Group LXXVI recites an antibody that binds to a polypeptide encoded by SEQ ID NO:1, Group LXXVII recites an antibody that binds to a polypeptide encoded by SEQ ID NO:2, Group LXXVIII recites an antibody that binds to a polypeptide encoded by SEQ ID NO:3,... ..and Group C recites an antibody that binds to a polypeptide encoded by SEQ ID NO:25.

Groups CI-CXXV, claim 6-8, drawn to the special technical feature of a method for detecting a polynucleotide. Group CI recites SEQ ID NO:1, Group CII recites SEQ ID NO:2, Group CIII recites SEQ ID NO:3,... ..and Group CXXV recites SEQ ID NO:25.

Groups CXXVI-CL, claim 17, drawn to the special technical feature of a method for generating a transcript image of a sample containing polynucleotides. Group CXXVI

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recites a microarray comprising at least 60 contiguous nucleotides of SEQ ID NO:1, Group CXXVII recites a microarray comprising at least 60 contiguous nucleotides of SEQ ID NO:2, Group CXXVIII recites a microarray comprising at least 60 contiguous nucleotides of SEQ ID NO:3,... ..and Group CL recites a microarray comprising at least 60 contiguous nucleotides of SEQ ID NO:25.

Groups CLI-CLXXV, claim 18, drawn to the special technical feature of a method for screening a compound for effectiveness in altering expression of a target polynucleotide. Group CLI recites SEQ ID NO:1, Group CLII recites SEQ ID NO:2, Group CLIII recites SEQ ID NO:3,... ..and Group CLXXV recites SEQ ID NO:25.

Groups CLXXVI-CC, claim 19, drawn to the special technical feature of a method for assessing toxicity of a test compound. Group CLXXVI recites a probe comprising at least 20 contiguous nucleotides of SEQ ID NO:1, Group CLXXVII recites a probe comprising at least 20 contiguous nucleotides of SEQ ID NO:2, Group CLXXVIII recites a probe comprising at least 20 contiguous nucleotides of SEQ ID NO:3,... ..and Group CC recites a probe comprising at least 20 contiguous nucleotides of SEQ ID NO:25.

[6] The special technical feature linking the inventions of Groups I-CC is a nucleic acid.

[7] The inventions listed as Groups I-CC do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

- According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. The polypeptides of Groups LI-LXXV lack a common structure, the polynucleotides of Groups I-XXV lack a common structure, and the antibodies of Groups LXXVI-C lack a common structure, and thus, the molecules share no special technical feature.
- According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The nucleic acids of Groups I-XXV, the polypeptides of Groups LI-LXXV, the transgenic organisms of Groups XXVI-L, and the antibodies of Groups LXXVI-C share no special technical feature as the nucleic acids of Groups I-XXV, particularly the nucleic acid of claim 3, encompasses nucleic acids that are not the same as the nucleic acid of the transgenic organisms of Groups XXVI-L and do not correspond to the polypeptide of Groups LI-LXXV and instead encompass nucleic acids that would encode polypeptides that would not elicit the antibodies of Groups LXXVI-C.
- 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention. Accordingly, the methods of Groups CXXVI-CLXXV do not have unity of invention with the polynucleotides of Groups I-XXV.
- The nucleic acids of Groups I-XXV are neither made nor used by the methods of Groups CI-CXXV and CLXXVI-CC.

[8] Claims 1-19 will be examined only to the extent the claims read on the elected subject matter.

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[9] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

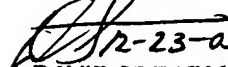
[10] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

Patent Examiner

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12-23-03
DAVID STEADMAN
PATENT EXAMINER